distinguishable sensing functions, one which monitors electrical activity, and one which monitors something else. Zacouto only monitors electrical activity of the heart, and therefore is not believed to be an anticipation of Claim 1. However, upon review of Claim 1, Applicant recognizes the argument that the electrical activity of the heart could be construed to be a physiological parameter. As such, the means for measuring a physiological parameter and the means for monitoring electrical activity in body tissue could be construed to alternately read upon that portion of the Zacouto device, which senses electrical activity of the heart. It is Applicant's position that such a reading of Claim 1 is unreasonable in view of the description in the specification. However, in view of this ambiguity, Applicant now believes Claim 1, as originally submitted, did not set forth the invention with sufficient specificity as required under 35 USC 112. Claim 1 has therefore been cancelled in favor of original Claim 6, which is believed to be sufficiently specific and unambiguous with regard to the invention. In addition, Applicant respectfully asserts that Claim 6 and the claims dependent from it are not anticipated by Zacouto.

The present invention is intended to provide a means for increasing or decreasing heart rate in response to detected cardiac output need of the patient. The need for such a device arises because the heart's own regulatory system for varying its rate in response to need for cardiac output has broken down. Zacouto's device paces when the heartbeat falls below a rate threshold which does not necessarily vary with actual cardiac need. The present device, unlike Zacouto's, is designed to pace when the patient's naturally occurring heartbeats do not reflect actual need for cardiac output and to remain inhibited when the patient's natural heartbeat does reflect actual need.

Claim 6 more narrowly focuses upon this aspect of the invention, by setting forth an implantable pacemaker which provides stimulating pulses only in the absence of naturally occurring heartbeats. This limitation in the preamble is set forth in the structure defined by the claim elements.

The Zacouto device measures the interval between two successive natural heart contractions, and adjusts the escape interval of the pacemaker in response thereto. Of course, this particular method of adjusting the escape interval takes effect only while the pacemaker is inhibited, as only then can the natural heartbeats be counted and measured. As such, during the time that the Zacouto device is pacing, it is incapable of utilizing this adjustment method to vary the escape interval of the device. As such, this particular function of the Zacouto pacer does not result in the pacer changing pacing rates in response to changes in demand for cardiac output, but only in response to detected changes in rate, and then only when the pacer is not itself pacing.

Even when the Zacouto device does succeed in measuring the interval between two adjacent naturally occurring heartbeats, this measurement is not necessarily related in any predetermined fashion to the actual demand for cardiac output by the patient. For example, the most likely event that would trigger the adjustment of an escape interval in Zacouto's pacemaker is the occurrence of a a PVC, which is not directly related to an increase in cardiac need.

Claim 6 is thus clearly distinguishable over the Zacouto reference in that it specifies a measuring means for measuring a parameter which is indicative of actual cardiac output need in the patient. As discussed above, this device is intended to be used in patients in which the patient's own

heartbeat does not reflect this actual physiological need. Therefore, measuring this heartbeat, as Zacouto does, does not provide a measurement of a parameter indicative of the need for cardiac output, and the Zacouto pacemaker does not thereby vary its rate in correspondence with the patient's need for cardiac output, as required by Claim 6.

Claims 7, 8, 10, 11 and 12, all dependent from Claim 6, are similarly not believed anticipated by Zacouto.

Claim 9 is a new independent claim which specifies that the measured parameter is a chemical parameter of venous blood which is indicative of need for cardiac output. This claim, including as it does the limitations of original Claim 6, is also believed not anticipated by the Zacouto reference.

Reconsideration of original claims remaining in the case, along with consideration of new claims is respectfully requested.

Respectfully submitted,

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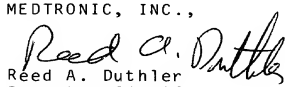

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